REMARKS

The Final Office action dated November 12, 2008 is acknowledged. Claims 1-8, 17-19, 21, 34 and 35 are pending in the instant application. According to the Final Office action, each of the presently pending claims has been rejected. The Applicant wishes to thank the Examiner for the withdrawal of the objection to the specification, the rejection of the claims as being indefinite and the rejection of the claims as being anticipated by Yates. By the present response, claims 1 and 34 have been amended and claims 2 and 3 have been canceled. It is noted that the subject matter of claims 2 and 3 have been incorporated into both independent claims 1 and 34. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

The Examiner has requested that the Application provide a certified translation of the Rompp Lexicon Chemie reference to hashish. Submitted herewith are two additional articles in English which related to "Cannabis" and "Hashish Oil." As set forth therein, cannabis oil (or hashish oil) is a concentrated, cannabinoid-containing extract prepared from cannabis plant material. Reference is also made to paragraph [0039] of Whittle, et al., which is cited in the present Final Office action as discussed below. The above notwithstanding, a certified English translation of Rompp Lexicon Chemie can be provided at the Examiner's request.

Priority

As requested by the Examiner, a certified English translation of the German priority application is enclosed herewith. It is noted that the text of the German application is identical to corresponding the PCT application. It is believed that this

submission will resolve the issue of priority discussed on page 2 of the Final Office action.

Objection to the Claims

The Examiner has objected to claim 1 for the typographical error "{consisting}." This matter has been addressed in the present amended claims. Withdrawal of this objection is respectfully requested.

Rejection of Claim 34 under 35 U.S.C. 112, first paragraph

Claim 34 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that claim 34 contains subject matter which was not described in the specification, i.e., that the term "a cannabis oil" constitutes new subject matter in that the specification does not support that cannabis oil is an embodied species of cannabis extract.

Claim 34 has been amended to be placed into independent form and is based on the subject matter of present claim 1. However, claim 34 pertains to "cannabis oil" while claim 1 pertains to "cannabis extract." It is submitted that amended claim 34 is supported by the specification and by original claim 1, which read "...a cannabis extract or a cannabis oil..." In addition, original claims 2 and 3 depend from original claim 1. The limitations of original claims 2 and 3 (i.e., the matrix polymers) are thereby properly set forth in current claim 34. In view of the above, it is submitted that claim 34, as amended, no longer suggests that cannabis extracts and cannabis oils would be synonymous or that cannabis oil would represent an embodied species of cannabis extract. Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-8, 17-19, 21, 34 & 35 Under 35 U.S.C. 103(a)

Claims 1-8, 17-19, 21, 34 & 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0136752 (Whittle, et al.). The Examiner argues in the Final Office action that Whittle, et al. disclose the limitations of the presently claimed invention, as discussed in detail on pages 7-10 of the present Final Office action. In particular, the Examiner states that Whittle, et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent. The Examiner acknowledges that Whittle, et al. fail to teach the overall administration form as conforming to the instantly claimed thickness limitations.

In this regard, the Examiner concludes that it would have been obvious to one skilled in the art to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form as taught by Whittle, et al. and to modify the thickness of the cast film form to produce the presently claimed invention. The Examiner further concludes that one skilled in the art would have been motivated to do so because Whittle, et al. expressly teach each of the aspects of the present invention and that optimization of the thickness parameter would have been *prima facie* obvious.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Final Office action. It is submitted that Whittle, et al. teach pharmaceutical preparations containing lipophilic drug substances such as cannabinoids. As set forth in paragraphs [0013] and [0014] therein, these preparations are based on gels which are formed by combining substances of opposite electrical charge. Suitable substances having negative or positive surface charge are listed in Table 2 (page 6) of Whittle, et al. In contrast, the polymer matrix of the mucoadhesive administration forms as presently claimed is prepared from polymers which are clearly different from the polymers taught by Whittle, et al.

With respect to the limitations recited in former claim 3 (now incorporated in claims 1 and 34), it was noted in the Final Office that Example 9 of Whittle, et al. teaches gum acacia (belonging to the group of natural gums). As noted above, the list of polymers included in amended claim 1 has been modified to exclude the specific polymers which are disclosed by Whittle, et al., including gum acacia. Therefore, Whittle, et al. fail to teach every feature of the present claims.

Considering the teaching of Whittle, et al. regarding the selection of polymers which are suitable for combination with cannabinoid-containing extracts (Table 2), it would not have been obvious for one skilled in the art to produce a pharmaceutical, mucoadhesive administration form which is based on the specific polymers defined in the present claims 1 and 34 and which contains a cannabis extract or cannabis oil within the polymer matrix formed by these polymers. Therefore, it is respectfully submitted that the presently claimed invention is not obvious in view of the cited prior art.

In view of the above, the teachings of Whittle, et al. fail to make the presently

claimed invention obvious. It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Whittle, et al., nor would one skilled in the art be motivated to modify Whittle, et al. to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: February 4 2009

By: _____
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Management of substance abuse

Cannabis

Terminology

Cannabis is a generic term used to denote the several psychoactive preparations of the plant *Cannabis sativa*. The major psychoactive consituent in cannabis is Δ-9 tetrahydrocannabinol (THC). Compounds which are structurally similar to THC are referred to as cannabinolds. In addition, a number of recently identified compounds that differ structurally from cannabinoids nevertheless share many of their pharmacological properties. The Mexican term 'marijuana' is frequently used in referring to cannabis leaves or other crude plant material in many countries. The unpollinated female plants are called *hashish*. Cannabis oil (hashish oil) is a concentrate of cannabinoids obtained by solvent extraction of the crude plant material or of the resin.

Epidemiology

Cannabis is by far the most widely cultivated, trafficked and abused illicit drug. Half of all drug seizures worldwide are cannabis seizures. The geographical spread of those seizures is also global, covering practically every country of the world. About 147 million people, 2.5% of the world population, consume cannabis (annual prevalence) compared with 0.2% consuming cocaine and 0.2% consuming opiates. In the present decade, cannabis abuse has grown more rapidly than cocaine and opiate abuse. The most rapid growth in cannabis abuse since the 1960s has been in developed countries in North America, Western Europe and Australia. Cannabis has become more closely linked to youth culture and the age of initiation is usually lower than for other drugs. An analysis of cannabis markets shows that low prices coincide with high levels of abuse, and vice versa. Cannabis appears to be price-inelastic in the short term, but fairly elastic over the longer term. Though the number of cannabis consumers is greater than opiate and cocaine consumers, the lower prices of cannabis mean that, in economic terms, the cannabis market is much smaller than the opiate or cocaine market.

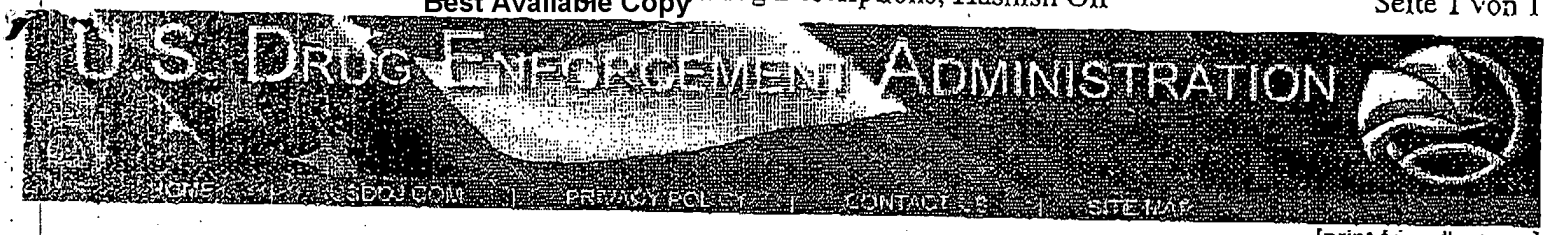
Acute health effects of cannabis use

The acute effects of cannabis use has been recognized for many years, and recent studies have confirmed and extended earlier findings. These may be summarized as follows:

- Cannabis impairs cognitive development (capabilities of learning), including associative processes; free recall of previously learned items is often impaired when cannabi is used both during learning and recall periods;
- Cannabis impairs psychomotor performance in a wide variety of tasks, such as motor coordination, divided attention, and operative tasks of many types; human performance on complex machinery can be impaired for as long as 24 hours after smoking as little as 20 mg of THC in cannabis; there is an increased risk of motor vehicle accidents among persons who drive when intoxicated by cannabis.

Chronic health effects of cannabis use

- selective impairment of cognitive functioning which include the organization and integration of complex information involving various mechanisms of attention and memory processes;
- prolonged use may lead to greater impairment, which may not recover with cessation of use, and which could affect daily life functions;
- development of a cannabis dependence syndrome characterized by a loss of control over cannabis use is likely in chronic users;
- cannabis use can exacerbate schizophrenia in affected individuals;
- epithetial injury of the trachea and major bronchi is caused by long-term cannabis smoking;
- airway injury, lung inflammation, and impaired pulmonary defence against infection from persistent cannabis consumption over prolonged periods;
- heavy cannabis consumption is associated with a higher prevalence of symptoms of chronic bronchitis and a higher incidence of acute bronchitis than in the non-smoking cohort;
- cannabis used during pregnancy is associated with impairment in fetal development leading to a reduction in birth weight;
- cannabis use during pregnancy may lead to postnatal risk of rare forms of cancer although more research is needed in this area



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Hashish Oil

The term hash oil is used by illicit drug users and dealers, but is a misnomer in suggesting any resemblance to hashish. Hash oil is produced by extracting the cannabinoids from plant material with a solvent. The color and odor of the resulting extract will vary, depending on the type of solvent used. Current samples of hash oil, a viscous liquid ranging from amber to dark brown in color, average about 15 percent THC. In terms of its psychoactive effect, a drop or two of this liquid on a cigarette is equal to a single "joint" of marijuana.

Translator's Certificate

I: Ina Langen

of Pützgasse 1, 50321 Brühl, Germany

do hereby certify that I am conversant with the English and

German

languages, and am a competent translator thereof, and I further certify that to the best of my knowledge and belief the attached document is a true and correct translation made by me of the documents in the

German

language attached hereto or identified as follows:

German patent application No. 102 26 494.5 as originally filed with and certified by the German Patent and Trademark Office

Dated this 12th day of February 2009

Ina Langen

(Signature of translator)

Für den Bezirk des
Oberlandesgerichts Köln
ermächtigte Übersetzerin
(3162 1219)

FEDERAL REPUBLIC OF GERMANY

Certificate of priority on the filing of a patent application

File Number:	**102 26 494.5**
Filing date:	14 June 2002
Applicant/Patentee:	LTS Lohmann Therapie-Systeme AG, Andernach/DE
Title:	Film-shaped mucoadhesive administration forms for administration of cannabis agents
IPC:	A 61 K 9/26

The copies appended hereto are a true and exact reproduction of the originally filed documents of this application.

Munich, this 4th day of April 2003
German Patent and Trademark Office
President
By order

[Seal]

[signature]

Ebert

Film-shaped mucoadhesive administration forms for administration of cannabis agents

The present invention relates to film-shaped, mucoadhesive administration forms which have a content of cannabis agents and which are suitable for administration of cannabis agents for therapeutic purposes. The invention further relates to the use of the said administration forms for treating conditions of disease in humans or animals.

The components of the Indian hemp plant (Cannabis sativa L.) have numerous pharmacological effects, of which the psychotropic effect is most widely known. Apart from this, cannabis components also have anti-emetic, anticonvulsive, muscle-relaxing, analgesic, sedative and appetite-increasing effects.
Because of the psychotropic or euphorizing effect and the dependency potential associated therewith, the therapeutic application of cannabis components is subject to severe restrictions.

It has long been known that cannabis components can be used with good effect for treating insomnia, neuralgias, painful rheumatism as well as gastric and intestinal disorders. A favourable therapeutic effect of cannabis components has furthermore been observed for the following indications:

Conditions of pain in cases of carcinosis and as a result of chemotherapy; conditions of pain and "wasting" syndrome in connection with AIDS; nausea and vomiting as side effects of a chemotherapy as well as in connection with AIDS or hepatitis; neuropathic pain; anorexia or cachexia, espe-

cially in connection with AIDS or carcinosis in the advanced stages.

Paralytic symptoms in connection with multiple sclerosis or traumatic transverse lesions; dystonic motor disturbance; bronchial asthma; epileptic attacks or generalized epilepsia; withdrawal symptoms in connection with alcohol dependence, benzodiazepine dependence and opiate dependence; Parkinson's disease; dementia, especially Morbus Alzheimer; nausea; arthritis; glaucoma; migraine; dysmenorrhoea.

At present, only the synthetically produced cannabis agent R-(6a,10a)-Δ-9-tetrahydrocannabinol (Dronabinol) is marketable. This isomer of tetrahydrocannabinol (THC) is sold under the product name Marinol; this medicament is administered orally in the form of capsules. Marinol is used for treating severe loss of weight in AIDS patients and cancer patients who as a result of chemotherapy suffer from heavy vomiting.

Apart from the aforementioned THC isomer, cannabis extracts and cannabis oils for therapeutic treatment purposes are also suitable. Application is usually effected via the oral route, e.g. in the form of capsules.

Cannabis extracts contain as pharmacologically active ingredients tetrahydrocannabinol (predominantly Δ-9-tetrahydrocannabinol, in small proportion: Δ-8-tetrahydrocannabinol), cannabidiol, cannabinol and cannabichromen. These active agents are also called cannabinoids (see the list "The Merck Index", 12th ed., 1996, page 285, No. 1794, as well as page 1573, No. 9349).

Oral administration of cannabis agents, especially of R-(6a,10a)-Δ-9-tetrahydrocannabinol, in the form of capsules,

tablets, pills or other solid, oral administration forms, or in the form of orally administered liquid preparations is disadvantageous for a variety of reasons:

- Since on use of the aforementioned administration forms, the absorption of the active agent takes place in the gastrointestinal tract, the time of onset of action is delayed. This is disadvantageous especially with respect to the indications mentioned, which generally require a quick onset of action (e.g. pain therapy).
- Cannabis agents are at least partially degraded and inactivated during the passage through the stomach and intestines under the influence of acid and enzymes, so that only part of the administered dose is absorbed and is systemically available.
- In this connection, unwanted plasma peak values may occur which are frequently the cause of side effects.
- In addition, after oral administration a significant portion of the active substance is already metabolised during the first passage through the liver ("first pass effect").

These disadvantages are particularly important with respect to the acceptance with which these medicaments are met in the above indicated indications. With the mentioned oral administration forms it is in addition of disadvantage that patients, in a particular given situation, regard the extended retention e.g. of a tablet or capsule (filled with an oily solution) in the mouth as particularly unpleasant.

It was therefore the object of the present invention to provide an administration form for the administration of cannabis agents which is free from the above-described disadvantages and which stands out in particular for its improved acceptance and compliance, as well as for advanta-

geous pharmacokinetic properties, especially for a rapid onset of action.

This object is achieved by a film-shaped, mucoadhesive administration form having a content of at least one active agent from the group of the cannabis agents, according to claim 1; further, preferred embodiments are described in the subclaims.
The object is furthermore achieved by the use of the film-shaped, mucoadhesive administration forms according to the invention in the treatment of diseases and symptoms.

The administration forms according to the invention are applied, preferably in the form of thin, small flat pieces or wafer-shaped objects ("wafers"), to the oral mucosa where they adhere because of their mucoadhesive properties. Application to the oral mucosa is preferably sublingual or buccal. Furthermore, other mucosal surfaces may also be taken into consideration as application site, e.g. the nasal mucosa.

During the period of application, the cannabis agent(s) contained in the administration form are released into the surrounding saliva and are subsequently absorbed by the oral mucosa (i.e. transmucosally). In the contact area of the application surface, the active agent may also be released directly from the administration form to the oral mucosa. During application, the administration form absorbs saliva and the active substance contained therein gets to the outside by diffusion.

It is advantageous in this connection that the active agent is released into the saliva after only a short time lag, so that the saliva-active agent mixture immediately reaches all areas of the oral mucosa, where it can be absorbed. The

amount of saliva in which the released active agent is dissolved or dispersed per unit of time is relatively small and there occurs no hypersalivation so that swallowing of the active agent (involving the mentioned disadvantages of gastrointestinal absorption) is largely excluded.
Since active agent absorption takes place by circumventing the gastrointestinal route, the above-described disadvantages (delayed onset of action, "first pass effect") of other oral administration forms (e.g. tablets) are avoided.

With the administration forms of the invention, compliance is increased as well, since application thereof requires no special discipline. Due to their small layer thickness the application of the film-shaped administration forms is generally not felt to be unpleasant by the treated persons.

According to a preferred embodiment, the administration forms of the invention comprise a polymer matrix which serves as active agent reservoir and has mucoadhesive properties. At least one layer or at least one surface of the administration form possesses mucoadhesive properties. The administration form may consist of one single layer or comprise a plurality of layers. In the case of a multilayer structure, at least one of the layers contains active agent(s).

In the simplest case, an administration form is made up of a mucoadhesive, preferably monolayer polymer matrix containing one or more cannabis agents. The active agent(s) may be present in the administration form in dissolved, dispersed or emulsified form.

The polymer matrix preferably contains one or more polymers which are water-soluble and/or swellable in aqueous media.

By selecting such polymers, it is possible to influence the mucoadhesive properties and the release behaviour.

Polymers of the following group are particularly suitable as water-soluble or swellable polymers: starch and starch derivatives, dextran; cellulose derivatives, such as carboxymethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl ethyl cellulose, sodium carboxymethyl cellulose, ethyl cellulose or propyl cellulose; polyacrylic acid, polyacrylates, polyvinyl pyrrolidones, polyethylene oxide polymers, polyacrylamides, polyethylene glycol, gelatine, collagen, alginates, pectins, pullulan, tragacanth, chitosan, alginic acid, arabinogalactan, galactomannan, agar-agar, agarose, carrageenan, and natural gums.

The polymer portion is preferably 5 to 95%-wt, especially preferably 15 to 75%-wt, relative to the dry matter of the administration form.

According to a preferred embodiment, the administration forms according to the invention contain a cannabis extract or a cannabis oil, preferably in an amount of 0.5 to 50%-wt, especially preferably in an amount of 1 to 30%-wt. Processes for the manufacture of pharmaceutically acceptable cannabis extracts or cannabis oils are known to those skilled in the art.

The invention furthermore comprises administration forms of the mentioned type containing at least one cannabinoid active agent from the group consisting of tetrahydrocannabinol, cannabinol, cannabidiol, and cannabichromen. Tetrahydrocannabinol, especially R-(6a,10a)-Δ-9-tetrahydrocannabinol, is particularly preferred as active agent. The

cannabinoid active agents may be of natural, partially synthetic or synthetic origin.
The active substance content preferably amounts to 0.1 to 20%-wt, especially preferably 0.5 to 10%-wt, relative to the dry matter of an administration form.
An individual administration form preferably contains 0.5 to 20 mg, especially preferably 1 to 10 mg of active agent, e.g. tetrahydrocannabinol.
Optionally, the administration forms according to the invention may contain one or more additives from the following groups: fillers, colourants, flavourings, aromatics, odorous substances, emulsifiers, plasticizers, sweeteners, preservatives, permeation-enhancing substances, pH regulators and antioxidants. Substances suitable for this purpose are in principle known to the skilled artisan.

It is of particular advantage to add flavourings, odorous substances and aromatics, either alone or in combination. It is, for example, possible to improve the impression of the taste by adding a refreshing flavouring (e.g. menthol, eucalyptol). This simultaneously enables inconspicuous intake of the medicament as it smells like a usual refreshment sweet. It additionally contributes to improving compliance.
Especially suitable are, for example, flavourings and aromatics from the group comprising menthol, eucalyptol, limonene, phenyl ethanol, camphene, pinene, seasoning aromatics such as n-butyl phthalide or cineol, as well as eucalyptus oil and thyme oil, methyl salicylate, turpentine oil, camomile oil, ethyl vanillin, 6-methyl coumarin, citronellol, and acetic acid n-butyl ester.

The inventive administration forms containing cannabis agents are film-shaped, i.e. of a thin and flat shape, for example in the form of thin, small flat pieces or small wa-

fers. These film-shaped plates may be of various geometric shapes, e.g. circular, ellipsoid or elongated.
Their thickness preferably amounts to 0.01 to 2 mm; with particular preference it is in the range of 0.05 to 0.5 mm. To avoid a foreign body sensation, the layer thickness should be as small as possible (preferably smaller than 0.2 mm).

To achieve special effects, the administration forms according to the invention may have a bilayer or monolayer structure. The individual layers may differ in terms of one or more of the following parameters: polymer composition, active substance content, active substance concentration, content of additives.

Due to the already mentioned properties, the cannabis agents-containing administration forms according to the invention can be employed to advantage in the treatment of diseases or symptoms, especially in cases of:
conditions of pain in cases of carcinosis and as a result of chemotherapy; conditions of pain and "wasting" syndrome in connection with AIDS; nausea and vomiting, especially nausea and vomiting as side effects of a chemotherapy as well as in connection with AIDS or hepatitis; neuropathic pain; anorexia or cachexia, especially in connection with AIDS or carcinosis in the advanced stages; paralytic symptoms in connection with multiple sclerosis or traumatic transverse lesions; dystonic motor disturbance; bronchial asthma; epileptic attacks or generalized epilepsia; withdrawal symptoms in connection with alcohol dependence, benzodiazepine dependence and opiate dependence; Parkinson's disease; dementia, especially Alzheimer's disease; nausea; arthritis; glaucoma; migraine; dysmenorrhoea.

CLAIMS

1. Film-shaped, mucoadhesive administration form having a content of at least one active agent from the group of the cannabis active agents.

2. Administration form according to claim 1, characterized in that it has a polymer matrix that serves as active substance reservoir and has mucoadhesive properties.

3. Administration form according to claim 2, characterized in that the polymer matrix contains one or more polymers which are water-soluble and/or swellable in aqueous media, said polymers preferably being selected from the group comprising starch and starch derivatives, dextran, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl ethyl cellulose, sodium carboxymethyl cellulose, ethyl cellulose or propyl cellulose, polyacrylic acid, polyacrylates, polyvinyl pyrrolidones, polyethylene oxide polymers, polyacrylamides, polyethylene glycol, gelatine, collagen, alginates, pectins, pullulan, tragacanth, chitosan, alginic acid, arabinogalactan, galactomannan, agar-agar, agarose, carrageenan, and natural gums, the polymer portion preferably being 5 to 95%-wt, especially preferably 15 to 75%-wt.

4. Administration form according to any one of the preceding claims, characterized in that it contains a cannabis extract or a cannabis oil, preferably in an amount of 0.5 to 50%-wt, especially preferably in an amount of 1 to 30%-wt.

5. Administration form according to any one of the preceding claims, characterized in that it contains at least one cannabinoid active agent from the group consisting of tetrahydrocannabinol, cannabinol, cannabidiol, and cannabichromen.

6. Administration form according to claim 5, characterized in that the mentioned substance(s) is/are contained in a proportion of 0.1 to 20%-wt, preferably in a proportion of 0.5 to 10%-wt.

7. Administration form according to any one of the preceding claims, characterized in that it contains tetrahydrocannabinol, preferably R-(6a,10a)-Δ-9-tetrahydrocannabinol, the active substance content preferably amounting to 0.1 to 20%-wt, especially preferably 0.5 to 10%-wt.

8. Administration form according to any one of the preceding claims, characterized in that it contains 0.5 to 20 mg, preferably 1 to 10 mg of active agent(s), preferably tetrahydrocannabinol.

9. Administration form according to any one of the preceding claims, characterized in that it contains one or more substances from the group of the flavourings, odorous substances and aromatics, especially from the group comprising menthol, eucalyptol, limonene, phenyl ethanol, camphene, pinene, seasoning aromatics such as n-butyl phthalide or cineol, as well as eucalyptus oil and thyme oil, methyl salicylate, turpentine oil, camomile oil, ethyl vanillin, 6-methyl coumarin, citronellol, and acetic acid n-butyl ester.

10. Administration form according to any one of the preceding claims, characterized in that the layer thickness thereof is 0.01 to 2 mm, preferably 0.05 to 0.5 mm.

11. Administration form according to any one of the preceding claims, characterized in that it contains one or more inactive ingredients from the group of the fillers, colourants, emulsifiers, plasticizers, sweeteners, preservatives, pH regulators, permeation-enhancing substances, and antioxidants.

12. Administration form according to any one of the preceding claims, characterized in that it has a multilayer structure, with at least one layer having an active agent content.

13. Use of an administration form according to one or more of the preceding claims for therapeutic treatment, especially for the treatment of: conditions of pain in cases of carcinosis and as a result of chemotherapy; conditions of pain and "wasting" syndrome in connection with AIDS; nausea and vomiting, particularly nausea and vomiting as side effects of a chemotherapy as well as in connection with AIDS or hepatitis; neuropathic pain; anorexia or cachexia, especially in connection with AIDS or carcinosis in the advanced stages; paralytic symptoms in connection with multiple sclerosis or traumatic transverse lesions; dystonic motor disturbance; bronchial asthma; epileptic attacks or generalized epilepsia; withdrawal symptoms in connection with alcohol dependence, benzodiazepine dependence and opiate dependence; Parkinson's disease; dementia, especially Alzheimer's disease; arthritis; glaucoma; migraine; dysmenorrhoea.

14. Use according claim 14, characterized in that the application is made onto the oral mucosa, especially sublingually or buccally.

ABSTRACT

A film-shaped, mucoadhesive administration form having a content of at least one active agent from the group of the cannabis agents is described.